The Impact of Gynecologic Pathology Diagnostic Errors on Patient Care

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Context

- Although CLIA ’88 mandates the performance of gynecologic cytologic-histologic correlation in all laboratories examining gynecologic cytology specimens for quality assurance purposes, practice experience reveals that these data are simply documented (“reviewed and filed”) and rarely used for quality improvement efforts.

Context

- Precluding meaningful use of these data for practice and patient safety improvement is a lack of knowledge (particularly among anatomic pathologists) regarding the nature and extent of the impact of these diagnostic discrepancies on patient management and outcomes.

Objective

- To obtain information regarding the clinical impact of gynecologic cytologic-histologic discrepancies on patient management and outcomes

Methods

- Design: Retrospective record review of patients with both a Pap test and a gynecological surgical specimen obtained within a 6-month period and with at least a “two-step”diagnostic discrepancy during the year 2002 at 4 different laboratories
- Setting: Three academic centers and one community hospital

Methods

- Participants: All patients during the year 2002 with original or review diagnoses of HSIL/CIN II or III or higher and a random sample of 10% of all patients with diagnoses of LSIL or lower
- Major outcome measures: 1) original correlation assessment of discrepancy as due to sampling or interpretation

Methods

- Major outcome measures: 2) specific clinical management procedure performed subsequent to clinician receipt of discrepant diagnoses, and 3) morbidity associated with clinical management procedures
- The clinical impact of each discrepancy event was categorically summarized either as “No Harm”, “Near Miss”, or “Harm”, with “Harm” sub-classified as minimal, moderate, or severe.

Error classification severity

No Impact on Care
No harm: Erroneous message not received
Near miss: Erroneous message received, but disregarded (choose one of the following)
False diagnosis occurred but was not acted on since correctly diagnostic specimen(s) were *collected at the same time* (using various sampling modalities)
Clinician acted regardless of *false negative* diagnosis
Clinician did not act on the *false positive* diagnosis

Impact on Care
Minimal harm:
Delay in diagnosis of less than 6 months not associated with morbidity
Otherwise unnecessary *non-invasive* further diagnostic efforts not associated with morbidity
Delay in therapy of less than 6 months not associated with morbidity
Otherwise unnecessary therapy based on diagnostic error not associated with morbidity
Mild harm:
Delay in diagnosis of 6 months or longer not associated with morbidity
Otherwise unnecessary *invasive* further diagnostic efforts not associated with morbidity
Delay in therapy of 6 months or longer not associated with morbidity
Minor morbidity lasting for any duration of time due to a delay in therapy
Minor morbidity lasting for any duration of time due to otherwise unnecessary diagnostic efforts
Minor morbidity lasting for any duration of time due to otherwise unnecessary therapeutic efforts
Moderate harm:
Moderate morbidity lasting for any duration of time due to a delay in therapy
Moderate morbidity lasting for any duration of time due to otherwise unnecessary diagnostic efforts
Moderate morbidity lasting for any duration of time due to otherwise unnecessary therapeutic efforts
Severe harm:
Loss of limb, other body part, organ or function of organ system due to otherwise unnecessary diagnostic efforts
Loss of limb, other body part, organ or function of organ system due to otherwise unnecessary therapeutic efforts
Loss of life due to unnecessary diagnostic efforts
Loss of life due to unnecessary therapeutic efforts

Unknown Impact on Care: Patient lost to follow-up or follow-up not documented; severity of harm cannot be determined

Definitions:
Minor morbidity – effects and events that can be demonstrated objectively (e.g. fever, thrombocytopenia, wound erythema, swelling, etc.) which do not require hospitalization or surgical intervention.
Moderate morbidity – effects and events that require hospitalization or surgical intervention, but do not result in loss of life, limb, other body part, organ or function of organ system

Results

Institutional and aggregated cytologic-histologic correlation errors

Project site	Number of gynecologic errors	Number of correlating cases	Error frequency using denominator of correlating cases	Total cytology workload	Error frequency using denominator of workload
A	139	1476	9.42	22,325	0.63
B	103	5748	1.79	72,641	0.14
C	430	9119	4.72	118,952	0.36
D	18	660	2.73	10,379	0.17
Aggregated	690		4.00		0.30

Results

Distribution of institutional errors by cause for error.

Specimen Type	Cause error		Project Site A N (%)	B N (%)	C N (%)	D N (%)	Aggregated (%)
Gynecologic	Interpretation	Cytology	4 (3)	7 (7)	195 (45)	3 (17)	40
		Surgical	3 (2)	2 (2)	23 (5)	0 (0)	
	Sampling	Cytology	110 (79)	37 (36)	114 (27)	15 (83)	60
		Surgical	23 (17)	61 (59)	126 (29)	0 (0)	

Results

Site	Review Cytology Diagnosis	Error Type	Patient Harm	Min Harm	Most prevalent management procedures performed
B	LSIL or lower N = 63	False negative N = 60 (77%)	Harm: 80% No Harm: 13% Unknown: 7%	69%	Repeat Pap: 59% Colpo + cx bx: 2% Colpo + cone: 13% (2 from false positives)
		False positive N = 3 (5%)	Harm: 100%	33%	
C	LSIL or lower N = 194	False negative N = 149 (77%)	Harm: 72% No Harm: 25% Unknown: 3%	79%	Repeat Pap: 63% Colpo + cx bx: 6% Colpo + cone: 12% (6 from false positives)
		False Positive N = 45 (23%)	Harm: 53% No Harm: 47%	88%	

Results

Site	Review Cytology Diagnosis	Error Type	Patient Harm	Min Harm	Most prevalent management procedures performed
B	HSIL or higher N = 37	False negative N = 36 (97%)	Harm: 81% No Harm: 14% Unknown: 5%	66%	Repeat Pap: 92% Colpo + cx bx: 2% Colpo + cone: 24% (1 from false positive)
		False positive N = 1 (3%)	Harm: 100%	0%	
C	HSIL or higher N = 100	False negative N = 48 (48%)	Harm: 71% No Harm: 29%	44%	Repeat Pap: 65% Colpo + cx bx: 6% Colpo + cone: 24% (11 from false positives)
		False Positive N = 52 (52%)	Harm: 79% No Harm: 21%	73%	

Conclusions

- Discrepant gynecologic cytologic-histologic diagnoses result in clinician management decisions that do result in harm to patients.
- The majority of harm is “minimal”, resulting from either a delay in diagnosis of less than 6 months or otherwise unnecessary noninvasive diagnostic procedures (additional Pap testing).
- However, a minority of cases (~ 10-30%) result in more clinically significant patient harm (e.g. otherwise unnecessary colposcopy procedures with invasive

Conclusions

- Given the body of literature describing the current lack of Pap test screening in particular female populations due to factors such as discomfort and embarrassment, from the patient point of view, having to undergo one or more unnecessary Pap tests due to poor sampling or pathologist interpretation would most likely not be considered “minimal harm”.

Conclusions

- Performing cytologic-histologic correlations in real time, rather than as a retrospective quality assurance process simply documenting numbers of false negative Pap tests, would decrease patient harm, particularly harm due to pathologist misinterpretation.

Conclusions

- A large opportunity exists for laboratories to improve patient safety and anatomic pathology practice by using both laboratory and clinical outcomes information related to cytologic-histologic discrepancies to guide quality improvement process changes.